Washington State Health Care Authority

Antivirals – HIV Combinations

Medical policy no. 12.10.99 Effective Date: August 1, 2020

Related medical policies:

- 12.10.99.02 Antivirals – HIV : emtricitabine alafenamide-tenofovir (Descovy)

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least ONE preferred regimen. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

Background:

Human immunodeficiency virus (HIV) is a single-stranded RNA retrovirus that attacks the immune system, specifically CD4+ T-helper cells, causing a progressive decrease in CD4+ T cell count and increased susceptibility of a person to infections. If left untreated, HIV can lead to acquired immunodeficiency syndrome (AIDS) which is the most severe phase of HIV infection. Approximately 1.1 million people in the U.S. live with HIV and about 14% of those living with HIV are unaware of their status. Although no cure for HIV currently exists, the use of antiretroviral therapy (ART) can help suppress the HIV virus and stop progression of the disease. ART therapy is recommended for all patients diagnosed with HIV to help protect the immune system and reduce the risk of serious health complications.

Medical necessity

Drug	Medical Necessity
Dolutegravir/lamivudine (**Dovato**) Dolutegravir/rilpivirine **(Juluca**) Lamivudine/tenofovir disoproxil (**Temixys**) Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) Doravirine/lamivudine/tenofovir disoproxil (**Delstrigo**) Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza**)	Fixed-dose combination ART therapy may be considered medically necessary for the following indications: • Used as a complete regimen for the treatment of HIV-1 infection in patients who have a contraindication or inadequate response to other HIV antivirals that are preferred on the Apple Health Preferred Drug List

Clinical policy:

Clinical Criteria	
Dolutegravir/lamivudine (**Dovato**)	**Dovato** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. HIV-1 treatment naïve; **AND** 3. If patient is of childbearing potential, a confirmed negative pregnancy test prior to initiation; **AND**

Preferred Alternatives: Dolutegravir (Tivicay) + Lamivudine	4. Tested and documented results of the presence of Hepatitis B virus (HBV) prior to initiation; **AND** 5. Absence of severe hepatic impairment (Child-Pugh Class C); **AND** 6. Creatinine clearance greater than or equal to 50 mL/min; **AND** 7. Justification for use of a single pill regimen over separate agents; **AND** 8. Dovato is not co-administered with dofetilide; **AND** 9. Prescribed by or in consultation with a specialist in infectious disease or HIV If **ALL** criteria are met, the request will be **approved for 12 months**
Dolutegravir/rilpivirine **(Juluca**) *Preferred Alternatives:* Dolutegravir (Tivicay) + Rilpivirine (Edurant)	**Juluca** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND**; 2. If patient is of childbearing potential, a confirmed negative pregnancy test; **AND** 3. Virologically suppressed with HIV-1 RNA < 50 copies/mL, and has been on a stable ART regimen for at least the past 6 months with no history of treatment failure on current regimen; **AND** 4. Justification for use of a single pill regimen over separate agents**; AND** 5. Juluca is not co-administered with either of the following: a. Dofetilide b. Carbamazepine c. Oxcarbazepine d. Phenobarbital e. Phenytoin f. Rifampin g. Rifapentine h. Dexamethasone i. St. John's Wort j. Proton Pump Inhibitors: esomeprazole, lansoprazole, omeprazole, pantoprazole, raberprazole 6. Prescribed by or in consultation with a specialist in infectious disease or HIV If **ALL** criteria are met, the request will be **approved for 12 months**
Lamivudine/tenofovir disoproxil (**Temixys**) *Preferred Alternatives:* Lamivudine +Tenofovir Disoproxil (Viread)	**Temixys** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Body weight is greater than or equal to 35 kg; **AND** 3. Tested and documented results of the presence of Hepatitis B virus (HBV) prior to initiation; **AND**

OR Lamivudine/tenofovir disoproxil (Cimduo)	4. Creatinine clearance greater than or equal to 50 mL/min; **AND** 5. Documented allergy to inactive ingredients contained in commercially separate agents and Cimduo; **AND** 6. Prescribed by or in consultation with a specialist in infections disease or HIV If **ALL** criteria are met, the request will be **approved for 12 months**
Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) *Preferred Alternatives:* Emtricitabine/tenofovir disoproxil (Truvada) + Dolutegravir (Tivicay) OR Emtricitabine/tenofovir disoproxil (Truvada) +Raltegravir (Isentress)	**Biktarvy** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Body weight is greater than or equal to 25 kg; **AND** 3. Patient is either treatment naïve or virologically suppressed with HIV-1 RNA < 50 copies/mL and has been on a stable ART regimen for at least the past 6 months with no history of treatment failure on current regimen; **AND** 4. Tested and documented results of the presence of Hepatitis B virus (HBV) prior to initiation; **AND** 5. Documentation that client is not a candidate for a tenofovir disoproxil based regimen due to contraindication or intolerance defined as any **ONE** of the following**:** a. Requires renal hemodialysis; **OR** b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months; **OR** c. Stabilized creatinine clearance (CrCL) between 60 – 89 mL/min, **AND** the client has hypertension, **AND** the client has at least **ONE** of the following: i. Diabetes; ii. Hepatitis C; iii. African American with family history of kidney disease; **OR** d. High risk for bone complications as determined by a history of **ONE** of the following: i. Vertebral compression factor; ii. Arm or hip fracture with minimal trauma; iii. Patients who have chronic kidney with proteinuria, low phosphate or is grade 3 or worse; iv. T-score ≤ -2.0 (DXA) at the femoral neck or spine; v. Chronic, high-dose glucocorticoid-therapy defined as more than 5 mg/day of prednisone or equivalent daily for greater than two (2) months **AND** documentation of the following are required for approval: 1. diagnosis requiring glucocorticoid regimen; 2. current glucocorticoid regimen;

	3. expected duration of therapy; **AND** 6. Biktarvy is not co-administered with dofetilide or rifampin. 7. Prescribed by or in consultation with a specialist in infectious disease or HIV If **ALL** criteria are met, the request will be **approved for 12 months**
Doravirine/lamivudine/tenofovir disoproxil (**Delstrigo**) *Preferred Alternatives:* Doravirine (Pifeltro) + Lamivudine/tenofovir disoproxil (Cimduo) OR Lamivudine + Tenofovir Disoproxil	**Delstrigo** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Tested and documented results of the presence of Hepatitis B virus (HBV) prior to initiation; **AND** 3. Patient is either treatment naïve or virologically suppressed with HIV-1 RNA < 50 copies/mL and has been on a stable ART regimen for at least the past 6 months with no history of treatment failure on current regimen; **AND** 4. Creatinine clearance greater than or equal to 50 mL/min; **AND** 5. Documented allergy to inactive ingredients contained in commercially separate agents and Cimduo; **AND** 6. Inability to maintain an undetectable viral load on preferred separate agents due to non-adherence; **AND** 7. Doravirine/lamivudine/tenofovir disoproxil is not co-adminstered with either of the following: a. Carbamazepine b. Oxcarbazepine c. Phenobarbital d. Phenytoin e. Enzalutamide f. Rifampin g. Rifapentine h. Mitotane i. St. John's Wort j. Any strong CYP3A inducer 8. Prescribed by or in consultation with a specialist in infectious disease or HIV If **ALL** criteria are met, the request will be **approved for 12 months**
Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) *Preferred Alternatives:* Lamivudine/tenofovir disoproxil (Cimduo) + Efavirenz OR Efavirenz + Lamivudine + Tenofovir disoproxil	**Symfi** or **Symfi Lo** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Patient is either treatment naïve or virologically suppressed with HIV-1 RNA < 50 copies/mL and has been on a stable ART regimen for at least the past 6 months with no history of treatment failure on current regimen; **AND** 3. Tested and documented results of the presence of Hepatitis B virus (HBV) prior to initiation; **AND**

	4. Body weight is greater than or equal to 40 kg for Symfi or greater than or equal to 35 kg for Symfi Lo; **AND** 5. Creatinine clearance greater than or equal to 50 mL/min; **AND** 6. Absence of severe hepatic impairment (Child-Pugh Class B or C); **AND** 7. Efavirenz/lamivudine/tenofovir disoproxil is not administered with Elbasvir/grazoprevir (Zepatier); **AND** 8. Justification for use of Symfi or Symfi Lo over commercially available separate agents showing inability to maintain adherence on preferred separate agents; **AND** 9. Prescribed by or in consultation with a specialist in infectious disease or HIV If **ALL** criteria are met, the request will be **approved for 12 months**
Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza)** <u>*Preferred Alternatives:*</u> Emtricitabine/Tenofovir Disoproxil (Truvada) + Darunavir/Cobicistat (Prezcobix) OR Emtricitabine/Tenofovir Disoproxil (Truvada) + Darunavir (Prezista) + Cobicistat (Tybost)	**Symtuza** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. If patient is of childbearing potential, a confirmed negative pregnancy test; **AND** 3. Tested and documented results of the presence of Hepatitis B virus (HBV) prior to initiation; **AND** 4. Absence of severe hepatic impairment (Child-Pugh Class C); **AND** 5. Body weight is greater than or equal to 40 kg; **AND** 6. Creatinine clearance greater than 30 mL/min; **AND** 7. Patient is treatment naïve **OR** virologically suppressed with HIV-1 RNA < 50 copies/mL and has been on a stable ART regimen for at least the past 6 months with no history of treatment failure on current regimen; **AND** 8. Documented allergy to inactive ingredients contained in commercially separate agents Truvada and Prezcobix; **OR** 9. Documentation that client is not a candidate for a tenofovir disoproxil based regimen due to contraindication or intolerance defined as any **ONE** of the following**:** a. Requires renal hemodialysis; **OR** b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months; **OR** c. Stabilized creatinine clearance (CrCL) between 60 – 89 mL/min, **AND** the client has hypertension, **AND** the client has at least **ONE** of the following: i. Diabetes; ii. Hepatitis C; iii. African American with family history of kidney disease; **OR**

d. High risk for bone complications as determined by a history of **ONE** of the following:
    i. Vertebral compression factor;
    ii. Arm or hip fracture with minimal trauma;
    iii. Patients who have chronic kidney with proteinuria, low phosphate or is grade 3 or worse;
    iv. T-score ≤ -2.0 (DXA) at the femoral neck or spine;
    v. Chronic, high-dose glucocorticoid-therapy defined as more than 5 mg/day of prednisone or equivalent daily for greater than two (2) months **AND** documentation of the following are required for approval:
        1. Diagnosis requiring glucocorticoid regimen;
        2. Current glucocorticoid regimen;
        3. Expected duration of therapy; **AND**

10. Symtuza is not co-administered with either of the following:
    a. Alfusozin
    b. Ranolazine
    c. Dronedarone
    d. Carbamazepine
    e. Phenobarbital
    f. Phenytoin
    g. Colchicine (if patient has renal or hepatic impairment)
    h. Rifampin
    i. Lurasidone
    j. Pimozide
    k. Ivabradine
    l. Ergot Derivatives
    m. Cisapride
    n. St. John's Wort
    o. Elbasivir/grazoprevir
    p. Lomitapide
    q. HMG-CoA Inhibitors: lovastatin, simvastatin
    r. Sildenafil
    s. Naloxegol
    t. Orally administered midazolam
    u. Triazolam
11. **Prescribed by or in consultation with a specialist in infectious disease or HIV**

	If **ALL** criteria are met, the request will be **approved for 12 months**
Drug Name	**Criteria (Reauthorization)**
Dolutegravir/lamivudine (**Dovato**) Dolutegravir/rilpivirine **(Juluca**) Lamivudine/tenofovir disoproxil (**Temixys**) Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) Doravirine/lamivudine/tenofovir disoproxil (**Delstrigo**) Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza**)	Fixed-dose combination ART therapy may be reauthorized if patient shows continued medication adherence defined as: a. No break in therapy as shown by consistent prescription claims history **OR;** b. No more than a 45 day gap between fills If the above criteria are met, the request will be approved for **12 months**

Dosage and quantity limits

Drug Name	Strength	Quantity Limit
Dovato	Dolutegravir 50 mg/lamivudine 300 mg	30 tablets per 30 day supply
Juluca	Dolutegravir 50 mg/rilpivirine 25 mg	30 tablets per 30 day supply
Temixys	Lamivudine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Biktarvy	Bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg	30 tablets per 30 day supply
Delstrigo	Doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Symfi	Efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Symfi Lo	Efavirenz 400 mg/lamivuidine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Symtuza	Darunavir 800 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg	30 tablets per 30 day supply

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History

Date	Action and Summary of Changes
09/17/2020	Updated reauthorization criteria
07/15/2020	Updated note section from "TWO preferred agents" to "ONE preferred regimen"
04/13/2020	New policy created